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10/559,879

08/30/2006

Harry John Wadsworth

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EXAMINER

VALENROD, YEVGENY

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/559,879 | Applicant(s) WADSWORTH ET AL. | |
| | Examiner YEVEGENY VALENROD | Art Unit 1621 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/07/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-16, in the reply filed on 11/13/08 is acknowledged.

Claim 17 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected product, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/13/08.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al (*Journal of Chemical Society, Perkin Transactions 1*, **1998**, 13, pp 2043-2046) in view of Lubinkowski et al. (*Journal of Organic Chemistry* **1975**, 40 p 3010).

Scope of prior art

Shah et al. teach preparation of fluoride-labeled aromatics using aryl iodonium salts as aryl bearing reagent and CsF or APE KF (same as Kryptofix, claim 5) as a source of fluoride (see Tables 1 and 2 on page 2044). Shah et al. describe their method having utility in preparation of fluorinated DOPA (see page 2-43, column 1,

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structure 1). The fluorine attached to the ring in Shah et al is an ^{18}F isotope (see page 2044, column 1, scheme 4). The product is purified via HPLC (page 2045, column 1, lines 4-7).

Difference between instant claims and Shah et al

Shah et al fail to teach radical trap in their process.

Secondary reference

Lubinkowski et al teach that radical side reactions can occur in SN type reactions of diaryliodonium salts (page 3010, column 1, second paragraph, lines 1-6). They also teach that such reactions can be suppressed by using a radical inhibitor such as 1,1-diphenylethylene (page 3010, column 2, line 3-7).

Obviousness

One skilled in the art, at the time the instant application was filed would have been motivated to use radical trap in the invention of Shah et al. Since the invention of Shah et al. is an SN type reaction involving a diaryliodonium salt one would be motivated to reduce byproduct formation due to radical reactions by using 1,1-diphenylethylene as taught by Lubinowski. The expected result of doing so would be reduction of byproducts due to radical reactions as demonstrated by Lubinowski in Table II on page 3011 where the product yield for PhOEt in the presence of DPE was increased 77% from 14% where no DPE was added.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al (*Journal of Chemical Society, Perkin Transactions 1*, **1998**, 13, pp 2043-2046) in view

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of Lubinkowski et al. (*Journal of Organic Chemistry* **1975**, 40 p 3010) as applied to claim 1 above, and further in view of Chen et al. (*Synlett*, **2000**, No8, 1175-1177).

Ascertaining the difference

Instant claim 7 has an additional limitation directed to the iodonium salt being immobilized on solid support.

Secondary reference

Chen et al teach preparation and utility of solid supported arylodonium salts.

Obviousness

One skilled in the arts would find it obvious to utilize solid support to perform the reaction of Shah et al. Motivation for doing so comes from the ease of manipulation and simplified purification procedures that have become associated with solid phase chemistry (Chen, page 1175, first column, first paragraph lines 1-3 and common knowledge of skilled artisan). Since Chen et al. have provided a method of preparing solid supported iodonium reagent, one skilled in the arts would find it obvious to utilize the described method for performing reactions that utilize said reagent in solution phase chemistry. Using solid support is therefore obvious absent unexpected results. Expected result is that the reaction will proceed in a manner similar to the corresponding solution phase reaction.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are provisionally rejected on the ground of nonstatutory

obviousness-type double patenting as being unpatentable over claims 1-15 of

copending Application No. 10/559,878 in view of Lubinkowski et al. (*Journal of Organic Chemistry* **1975**, 40 p 3010).

Scope of claims of '878

'878 claims a method for production of aromatic fluorine-labeled compound that is the same compound as is produced by the instantly claimed method. '878 utilized the same iodonium salt as is utilized in the instant claims.

Ascertaining the difference

'878 fails to disclose a radical trap.

Secondary reference

Lubinkowski et al teach that radical side reactions can occur in SN type reactions of diaryliodonium salts (page 3010, column 1, second paragraph, lines 1-6). They also

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teach that such reactions can be suppressed by using a radical inhibitor such as 1,1-diphenylethylene (page 3010, column 2, line 3-7).

Obviousness

One skilled in the art, at the time the instant application was filed would have been motivated to use radical trap in the invention of '878. Since the invention of '878 is an SN type reaction involving a diaryliodonium salt one would be motivated to reduce byproduct formation due to radical reactions by using 1,1-diphenylethylene as taught by Lubinowski. The expected result of doing so would be reduction of byproducts due to radical reactions as demonstrated by Lubinowski in Table II on page 3011 where the product yield for PhOEt in the presence of DPE was increased 77% from 14% where no DPE was added.

This is a provisional obviousness-type double patenting rejection.

Conclusion

Claims 1-17 are pending.

Claim 17 is withdrawn

Claims 1-16 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yevgeny Valenrod/

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